



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndt	0050/49860	8414
26474	7590	05/13/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER

1615

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,313	BERNDL ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Remarks/Amendment dated 02/09/04.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 10 – 12, and 14 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth et al (USPN 5,741,524 hereafter '524), Sutton et al (USPN 5,93,805 hereafter '805) and Groenendaal et al (USPN 5,264,222 hereafter '222). The claims drawn to a process of making an excipient by spray-drying a solution of a polymer and a surface active agent in order to make a free-flowing powder. Also the surfactant can be selected from ethoxylated sorbitan fatty acids esters. The excipient further includes dyes, waxes and other common tableting agents. The excipient has a particle size between 10 and 1000 microns. The surfactant has a drop point range from 20 to 40°C, and an HLB from 10-15.
4. '524 teaches an improved excipient for tableting. The excipient can be wet-granulated and dried using known methods such as tray drying, spray drying, etc. (col. 2, lin. 14 – 23), though it is preferred that the product is spray dried (col. 14, lin. 28 – 32). The excipient includes a non-ionic surface-active agent. The excipient further includes dyes and other tableting

Art Unit: 1615

agents (col. 12, lin. 11 – 40). In one embodiment, the formulation comprises polyvinylpyrrolidone (col. 18, lin. 43), which is included as a further lubricant. The particles of the resultant free-flowing powder are between 10 and 1000 microns (col. 14, lin. 51 – 60). What is lacking however, is the disclosure of polyvinylpyrrolidone as the polymer undergoing processing.

5. '524 however discloses microcrystalline cellulose as the improved excipient polymer. However, microcrystalline cellulose and polyvinylpyrrolidone are common disintegrants well known in the art, and can be substituted for one another. This is evidenced by '222, which discloses an oral formulation comprising disintegrants crosslinked polyvinyl pyrrolidone and microcrystalline cellulose (col. 2, lin. 25 – 29). A skilled artisan would have been motivated to substitute pvp into the process steps of '524 in order to avoid possible agglomeration associated with the use of microcrystalline cellulose.

6. The reference is also silent to the drop point of the surfactant, though ethoxylated sorbitan fatty acids esters are disclosed. It is the position of the examiner that the drop point of these surfactants would be inherent to the ethoxylated sorbitan fatty acid esters recited in '524.

7. Another deficiency in '524 is a disclosure of the specific surfactant of claim 16. '805 discloses an excipient comprising a polymer and surfactants. The polymers include polyvinyl pyrrolidone and glycerol-polyoxyethylene ricinoleate (col. 7, lin. 40 – 65). The selection of a particular surfactant is well within the level of skill in the art. '805 discloses many of the same surfactants as '524 and a skilled artisan would expected the surfactant to perform satisfactorily since they are listed together and perform the same task of stabilizing the formulation.

Art Unit: 1615

Regarding the limitations of claims 14 and 17, reciting the specific concentrations of surfactant in the excipient, it is the position of the examiner that such limitations do not impart patentability in view of the prior art. '524 discloses the surfactant being present as much as 20% by weight of the polymer. The general conditions of the limitations are met by these disclosures. It is the position of the examiner that the determination of these ranges is well within the level of ordinary skill in the art and can be determined through routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

8. With these aspects in mind it would have been obvious to a skilled artisan to combine the disclosures of '524, 805 and '222. A skilled artisan would have included the crosslinked pvp or '222 into the process steps of '524 in order to avoid possible instability and premature agglomeration issues associated with the use of microcrystalline cellulose. A skilled artisan would have seen from '222 that cross-linked pvp is a well known disintegrant and is easily substitutable with microcrystalline cellulose. A skilled artisan would have been motivated to combine the surfactant of '805 in order to provide proper stability of to the excipient. It would

Art Unit: 1615

have been well within the level of skill to make the addition with an expected result of, a stabilized excipients, since '524 and '805 share many of the same possible surface active agents. It would have been well within the level of skill in the art to combine the disclosures as such with an expected result of a free-flowing excipient useful in pharmaceutical dosage forms.

Response to Arguments

9. Applicant's arguments with respect to claims 10-20 have been considered but are moot in view of the new ground(s) of rejection. However regarding applicant argument that the combination does not address the issue of dosing (handling larger amounts of liquid), the examiner reminds applicant that these features are not represented in the claims. The claims are simply drawn to a method of making a free-flowing excipient comprising a polymer and a surfactant. The stickiness of the excipient is not recited within the scope of the instant claims, and is not given patentable weight as such.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1615

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600